COMMISSIONER'S DECISION

INSUFFICIENT DISCLOSURE S.36(1): No Invention Apart From Compounds Lost in Conflict.

There is no adequate disclosure of the invention claimed. The disclosure does not reveal any unexpected synergism, or adequate details of the operation, use or effect of an invention, such as required by S.36(1).

FINAL ACTION: Affirmed

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Patent application 081,556, Cl. 167/213 was filed on April 30, 1970 by CIBA Ltd. for an invention made by George deStevens and Lincoln Harvey Werner and entitled "3:3-DIHYDRO-1:2:4-BENZOTHIADIAZINE-1:1-DIOXIDES AND PROCESS FOR THEIR MANUFACTURE." The examiner issued a final rejection of the application on January 8, 1973 on the ground that the applicant already had a Canadian patent for the same invention. Under Rule 46(5) the applicant requested a review and hearing before the Patent Appeal Board. This was conducted on May 8, 1974, at which time Mr. George Seaby represented the applicant.

Claims 1 and 9 illustrate the nature of the invention being claimed:

> Cl. 1 A pharmaceutical composition comprising 6-chloro-3-chloromethyl-2-methyl-7-sulfamyl-3, 4-dihydro-1, 2,4-benzothiadiazine-1, 1-dioxide or a pharmaceutically acceptable salt thereof together with a hypotensive agent.
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> Cl. 9 A pharmaceutical composition as claimed in any one of claims 1, 2 and 6, including also a pharmaceutically acceptable carrier.

It will thus be seen that the applicant is claiming a composition consisting of a particular (and novel) benzothiadiazine mixed with a hypotensive agent, and in some instances that same composition mixed with a carrier. The precise chemical structure of the benzothiadiazine is immaterial for our consideration, and we will hereafter refer to it as "benzothiadiazine." The benzothiadiazine has diuretic properties which make it useful as a medicament.

The application is a division of application 789,817, now Canadian Patent 851,197, which issued on Sept. 8, 1970 to the same applicant. In it the same benzothiadiazine was claimed. Since Section 41 was applicable, the claim for the benzothiadiazine in the patent was restricted to the process by which it is prepared. In this application the diuretic mixture is not restricted to any process of manufacture. In both the patent and this application it was disclosed that the benzothiadiazine could be administered medicinally mixed with various inert pharmaceutical substances (e.g. water, starches, alcohols and talc) or with other therapeutically useful substances, such as hypotensive agents (which reduce high blood pressure). Typical of the hypotensive agents are rauwolfia, reserpine and hydralazine.

In rejecting the application the examiner took the position that there was no invention disclosed relating to the mixture of the benzothiadiazine with hypertensive agents beyond that disclosed for benzothiadiazine itself, and relied upon the holding of the courts in Commissioner of Patents v. Farbwerke Hoechst (1964) S.C.R. 49 to support his contention that under such circumstances a second patent should not be granted. He also applied Section 41 of the Patent Act. His arguments were couched in the following terms:

> When an applicant has already received a patent for a novel active ingredient (such as in Canadian Patent 851,197 above), he is not entitled to a second Patent covering the novel ingredient in association with a conventional additive, when there is no teaching in the disclosure that such a mixture amounts to a second or separate invention (such as is now claimed in this application).
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> The application is governed by Section 41. The compound is new, In such circumstances applicant cannot obtain protection of the type he is seeking here, when he already has protection by way of process claim and product claims restricted to the process by which the product was made. Also of course the compound is a medicine and was made by a chemical process. The protection obtained in the Canadian patent 851,197 is all the protection applicant is entitled to. Hoechst has ruled that when a legal impedement exists against

> a new compound then this legal impedement cannot be avoided by submitting claims to a mere admixture of the new compound and a conventional additive.

The report also included an exhaustive analysis of the factual situations present both here and in the Farbwerke Hoechst appeal, and makes the point that the compositions claimed here are analagous to those refused in Farbwerke Hoechst.

It was the applicants contention that this application distinguishes from Farbwerke Hoechst because the benzothiadiazine is mixed with an active ingredient, rather than an inactive carrier. In his response to the Final Rejection and in his Appeal Brief he made (inter alia) the following submissions.

> While the applicants agree with the Examiner's interpretation of the Hoechst decision, they do not agree that it applies to the present case. The decision would certainly apply had applicants presented claims to the new diuretic and natriuretic 6-chloro-3-chloromethyl-2-methyl-7-sulfamyl-3,4-benzothiadiazine-1,1-dioxide and an orally ingestible pharmaceutically acceptable carrier, i.e., claims of the type presented in the adjucated Hoechst application.
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> Applicants clearly have not presented such claims; their claims read on a pharmaceutical composition comprising 6-chloro-3-chloromethyl-2-methyl-7-sulfamyl-3,4-dihydro-1,2,4-benzothiadiazine-1,1-dioxide and a hypotensive agent, i.e. two compounds with pharmacologically different activities, and not just a "conventional additive", the meaning of which is stretched by the Examiner far beyond what has been adjucated by the Supreme Court in the Commissioner vs. Hoechst. Obviously, the Examiner extends the meaning of that decision to include the combination of two pharmacologically different compounds. There is no authority in Canadian Law, which would support the Examiner's position and applicants are, therefore, of the opinion, that a withdrawl of the rejection is clearly called for.
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> Although this question was not raised by the Examiner, at least not explicitly, applicants would like to note, that the disclosure on page 2, line 25 to page 3, line 2 clearly supports the claims now in the application; in other words, the claims are not broader than the disclosure. Furthermore, the same claims have been included in the parent application Serial No. 789,817 (now patent 851,197) prior to the filing of the present divisional application. The continuity has,

> therefore, been secured; the present application dates back to the filing date of the parent application Serial No. 789,817 and, therefore, back to the filing of the US applications Serial No. 786,062, filed January 12, 1959 and Serial No. 846,779, filed October 16, 1959.
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> The second last paragraph of the Final Action appears to introduce new grounds for rejecting this application, namely that this application is governed by Section 41, and consequently applicants cannot obtain protection of the type sought herein. A Final Action should not introduce new grounds for rejecting an application.

It is of significance that the parent application was in conflict with application 798,497, now patent 795340, filed by one Leo R. Swett, assigned to Abbot Laboratories. Mr. Swett was the successful party in the conflict proceedings, and was awarded claims to the benzothiadiazine when prepared by reacting 4-amino-6-chloro-3 (methylsulfamyl)-benzene-sulfonamide with chloroacetaldehyde. The grant of a patent now to deStevens et al for claims to the benzothiadiazine when mixed with hypotensive agents (and unrestricted to any process of manufacture) would, in the absence of a licence, prevent Swett from utilizing his invention in such compositions. It is important, consequently, to be certain that deStevens et al had in fact made and disclosed a further invention, and are entitled to a patent which could prevent the earlier inventor, Swett, from utilizing his invention when mixed with hypotensive agents. As was said in the Farbwerke Hoechst case (supra), p.54:

> The claim to a pharmaceutical composition with which the present appeal is concerned is free from the limitations imposed by S.41(1) and a person who obtained a patent in this way could assert such claims against anyone using the pharmaceutically active ingredient constituting the substance of the invention regardless of the process whereby it was produced.

Because of the role the Farbwerke Hoechst case has played in the prior prosecution, it will be useful to quote the most pertinent portion of Mr. Justice Judson's remarks:

> A person is entitled to a patent for a new, useful and inventive medicinal substance but to dilute that new substance once its medical uses are established does not result in further invention. The diluted and undiluted substance are but two aspects of exactly the same invention. In this case, the addition of an inert carrier, which is a common

> expedient to increase bulk, and so facilitate measurement and administration, is nothing more than dilution and does not result in a further invention over and above that of the medicinal itself. If a patent subsists for the new medicinal substance, a separate patent cannot subsist for that substance merely diluted. If a legal impediment exists against a patent claim for the new medicinal substance, namely. S.41(1) of the Patent Act, that legal impediment is equally applicable to the diluted substance. The diluted medicinal is still a medicine and the essential step of the process for preparing the diluted medicinal is a chemical step. Therefore, S.41(1) of the Patent Act applies. Further, the respondent has already received patent protection to the full extent allowed by the law. Invention may lie in a new, useful, and inventive process for producing a new medicinal substance, and the respondent has already obtained patents for such inventive processes and for the new product as produced by such processes. The process claims and process dependent product claims in these patents represent the full extent of the protection to which the respondent is entitled.

The applicant has argued that his claims distinguish from the matter before the Court in Farbwerke Hoechst because his additives (the hypotensive agents) are not inert carriers. He has argued that a further invention is present because the admittedly new mixture of benzothiadiazine with hypotensive agents has a new pharmacological effect which is greater than the additive effect of its components. Such a synergistic effect might justify a second patent if the synergistic effects were unexpected. (cf. In re Huellmantel, 139 U.S.P.Q.496, 1963.) In support of that contention the applicant has supplied copies of scientific publications discussing the properties of the admixture. All of them, however, appeared well after the effective filing date of the application.

The examiner for his part has conceded the possibility of invention in admixtures where unobviousness is present. The essence of his argument, as we see it, is that no such unobviousness has been shown in this disclosure, and since on the basis of the disclosure the admixture must be considered conventional, what is claimed comes within the scope of Farbwerke Hoechst. That, incidentally, was the position taken when the same claims were rejected in the parent application on December 9, 1969, under Rule 25.

It thus becomes important to look to that disclosure. It is identical with that of the parent application (now patent 851197) from which it derives its divisional status. The seven pages of text are concerned primarily with the benzothiadiazine compound and the manner in which it is manufactured. The sole example is directed to such a manufacture. There is also included the following paragraph (underlining added).

> The new compounds are to be used as medicaments in the form of pharmaceutical preparations which contain these compounds in admixture with a pharmaceutical organic or inorganic, solid or liquid excipient which is suitable for enteral, for example, oral, or parenteral administration. To make up the preparations there may be employed substances which do not react with the new compounds, such as, for example, water, gelatine, lactose, starches, stearyl alcohol, magnesium atearate, talc, vegetable oils, benzyl alcohols, gums, propylene glycol, polyalkylene glycols or any other known excipient. The pharmaceutical preparations may be in the form, for example, of tablets, dragees, or capsules or in liquid form as solutions, suspensions or emulsions. They may be sterilized and/or contain auxiliary substances, such as preserving, stabilizing, wetting or emulsifying agents, salts for varying the osmotic pressure or buffers. <u>They may also contain other therapeutically useful substances, for example, hypotensive agents, such as Rauwolfia or Veratrum alkaloids, for example reserpine, rescinnamine, deserpidine, semi-synthetic Rauwolfia analogs, for example syringopine, germine or protoveratrine, synthetic hypotensive agents, for example, hydralazine, di-hydralazine, or ganglionic blockers, such as chlorisoldamine.</u>

The only reference to the purported invention being claimed appears in the last sentence of this paragraph (which has been underlined).

While it may be possible for a single sentence to provide sufficient disclosure to warrant claims to some inventions, we do not think that can be the case here. There is no indication in it of any unexpected synergism, or adequate details about the operation use or effect of the invention. Clearly Section 36(1) is not satisfied. In <u>Radio Corporation of America v. Raytheon Manufacturing</u> (1956-1960) Ex. C.R. 98 at 108, it was stated, for example, that:

It is a cardinal principle of patent law that an inventor may not validly claim what he has not described. In the patent law jargon it is said that the disclosures of the specification must support the claims. If they do not, the claims are invalid. Moreover, there is a statutory duty of disclosure and description that must be complied with if a claim for an invention is to stand. Section 35 of The Patent Act, 1935, provides, in part:

"35. (1) The applicant shall in the specification correctly and fully describe the invention and its operation or use as contemplated by the inventor, and set forth clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most closely connected, to make, construct, compound or use it. In the case of a machine he shall explain the principle thereof and the best mode in which he has contemplated the application of that principle. In the case of a process he shall explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions. He shall particularly indicate and distinctly claim the part, improvement or combination which he claims as his invention.

(2) The specification shall end with a claim or claims stating distinctly and in explicit terms the things or combinations which the applicant regards as new and in which he claims an exclusive property or privilege."

In Minerals Separation North American Corporation v. Noranda Mines Limited[1] I had occasion to consider the duties of disclosure required of an inventor in consideration of the grant of a valid monopoly in respect of his invention. At page 316, I said:

"Two things must be described in the disclosures of a specification, one being the invention, and the other the operation or use of the invention as contemplated by the inventor, and with respect to each the description must be correct and full. The purpose underlying this requirement is that when the period of monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application. The description must be correct; this means that it must be both clear and accurate. It must be free from avoidable obscurity or ambiguity and be as simple and distinct as the difficulty of description permits. It must not contain erroneous or misleading statements calculated to deceive or mislead the persons to whom the specification is addressed and render it difficult for them without trial and experiment to comprehend in what manner the invention is to be performed. It must not, for example, direct the use of alternative methods of putting it into effect if only one is practicable, even if persons skilled in the art would be likely to choose the practical method.

[1] (1947) Ex. C.R. 306

> The description of the invention must also be full; this means that its ambit must be defined, for nothing that has not been described may be validly claimed. The description must also give all information that is necessary for successful operation or use of the invention, without leaving such result to the chance of successful experiment, and if warnings are required in order to avert failure such warnings must be given. Moreover, the inventor must act uberrima fide and give all information known to him that will enable the invention to be carried out to its best effect as contemplated by him."
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> and I cited the cases from which this statement was abstracted. The statutory requirement then in effect was section 14 of The Patent Act, Statutes of Canada, 1923, Chapter 23, and I made the statement that it merely puts the requirements of the law, as laid down in the cases, into statutory form. While my judgment in the Minerals Separation case (supra) was reversed, the statement I have cited has not been challenged. And it is applicable in a case to which section 35 of The Patent Act, 1935, applies: vide Di Fiore v. Tardi[1]. The onus of disclosure that the section places on an inventor is a heavy and exacting one. (underlining added)

The same theme was developed in French's Complex Ore v Electrolytic Zinc 1930 S.C.R. 462, Smith Incubator v. Sealing 1937 S.C.R. 251, Minerals Separation v. Noranda Mines 1947 Ex. C.R. 306 at 316 and Gilbert v. Sandoz (1971) 64 C.P.R. 7 at 42-45.

As for the evidence now presented that invention is (or may be) present, we would refer to the statement of the President of the Exchequer Court in Riddell v Patrick Harrison 1956-60 Ex. C.R. 213 at 225:

> ...what has to be considered in a patent case is the invention as described in the specification and defined in the claims rather than that described in the evidence."

We think the matter might well be left as one of insufficiency to satisfy Section 36 of the Patent Act. The examiner went further on the basis that since no further invention was disclosed, the subject matter claimed is but another aspect of the invention that was disclosed, and another patent should not issue for that invention. On that ground the findings in Farbwerke Hoechst might conceivably apply, but we see no need to consider that issue in detail.

1. (1952) Ex. C.R. 149 at 154

The applicant has objected to the reference in the Final Action to Section 41, on the basis that new grounds for rejecting should not be introduced at the Final Rejection stage of proceedings. Section 41 was, however, raised in the previous report of the examiner. It was applied against exactly the same claims when they were present in the parent application, now patent 851197, on June 21, 1968. Furthermore the nature of the invention is such that Section 41 must obviously be a background consideration. Since, however, we have reached a conclusion that the first grounds of rejection made by the examiner is adequate, we see no need to pursue this point further.

For the reasons indicated, the Board is of the opinion that the rejection of the examiner should be confirmed.

G.A. Asher,
Chairman,
Patent Appeal Board.

I concur with the findings of the Patent Appeal Board. The application is refused. The applicant has six months within which to appeal this decision under the provisions of Section 44 of the Patent Act.

Decision accordingly,

A.M. Laidlaw,
Commissioner of Patents.

Dated at Hull, Quebec
this 2nd. day of August,
1974.

Agent for Applicant

Marks & Clerk
Ottawa, Canada